IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ditter, et al.
Appl. No.	:	10/603,425
Filed	:	June 24, 2003
For	:	LAMINATES OF ASYMMETRIC MEMBRANES
Examiner	:	Chevalier, A. A.
Group Art Unit	:	1772

DECLARATION OF I-FAN WANG, PH.D.

Dear Sir:

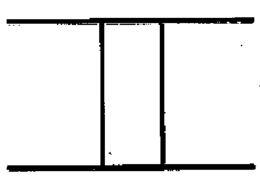
I, I-fan Wang, declare as follows:

1. I am a co-inventor of the subject application. I have a Ph.D. in membrane science and 23 years of experience working in research and development on membranes. During the last 12 years I have worked for the Pall Corporation (and/or its predecessor companies) and have studied and synthesized many different kinds of membranes.

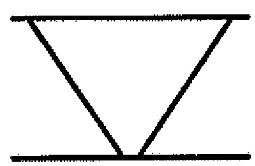
2. I am familiar with the prosecution history of U.S. Patent Application No. 10/603,425. I understand that the pending claims have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,983,288 (hereinafter "Karbachsch") in view of U.S. Patent No. 4,906,371 (hereinafter "Miller").

3. Membranes can be prepared having various pore structures. Claim 1 as currently amended is directed to a filter laminate having "a first membrane layer comprising a first membrane, wherein said first membrane is a microporous or ultraporous asymmetric membrane, said first membrane having a first surface and a second surface, each of said surfaces comprising pores, and a support region between said first surface and said second surface, said first membrane comprising an asymmetric region comprising flow channels that gradually increase or decrease in diameter from a point in said support region to said second surface, said first membrane further comprising an isotropic region in addition to said asymmetric region, such that said support region comprises a thickness between said first surface and said second surface, wherein said thickness comprises said isotropic region between said first surface and a point

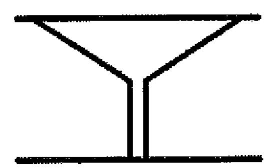
within said support region, and an asymmetric region between said point and said second surface, wherein said isotropic region comprises flow channels that are substantially constant in diameter from said first surface to said point between said isotropic region and said asymmetric region, and wherein said asymmetric region comprises flow channels that gradually increase or decrease in diameter from said point to said second surface." A pore structure such as the one recited in Claim 1 wherein the membrane has an asymmetric region and an isotropic region is commonly referred to as a "filter-with-a neck" structure. For purposes of comparison, an "isotropic" structure is characterized by generally uniform pore sizes throughout the thickness of the membrane, and a classic "asymmetric" structure is characterized by a dense layer of pores situated at the surface of the membrane with gradually widening flow channels through the thickness of the membrane. To illustrate the differences in pore morphology of these membrane structures, the structures are schematically depicted below. The drawings are meant only to show general differences of pore size distribution through the cross section of different membrane types, and are not necessarily to any particular scale.



Isotropic Structure



Classic Asymmetric Structure

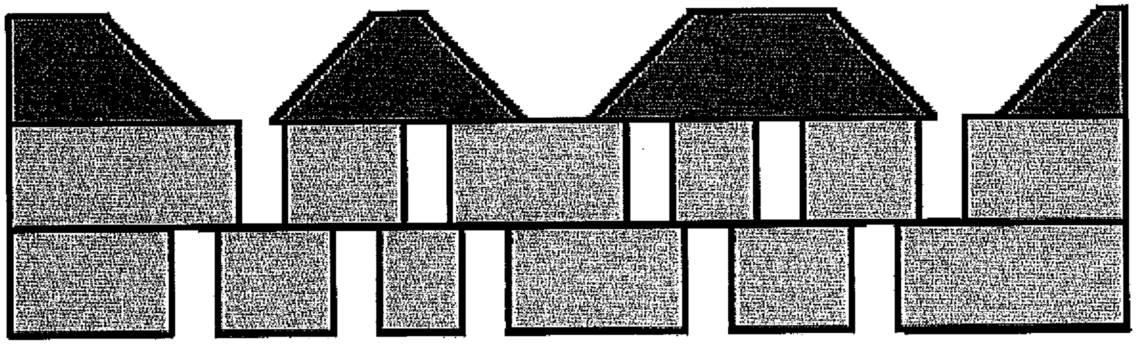


Funnel-with-a-Neck Structure

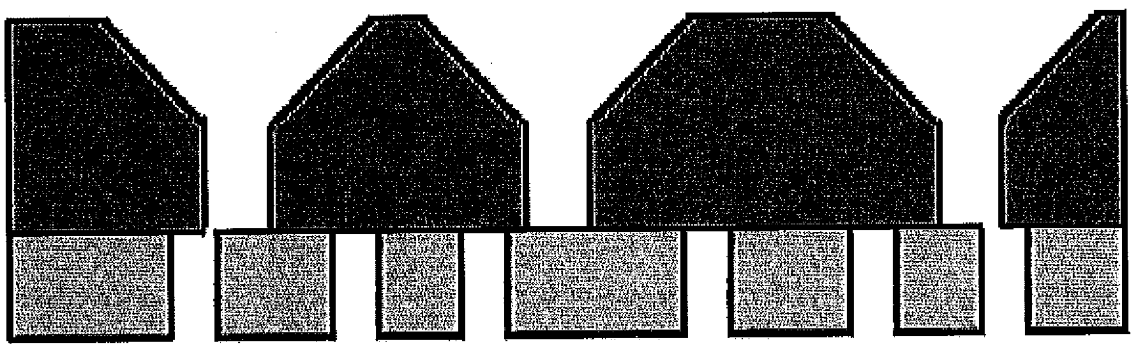
3. I was one of the first inventors of membranes having a funnel-with-a-neck pore morphology (see U.S. Patent No. 5,834,107, incorporated by reference in the present application). Membranes having a funnel-with-a-neck structure exhibit superior performance in certain aspects when compared to membranes having other pore morphologies. For example, the lateral wicking time is a function of the capillary action that occurs in the horizontal direction of the membrane. Capillary action is greatest in regions where the membrane's pore sizes are relatively small. In principle, lateral wicking is optimal in a purely isotropic membrane of relatively narrow pore size. Throughout the entire depth of such an isotropic structure, the layers extending in the horizontal direction all contain small pores, which are capable of exerting a relatively strong capillary force. As a result, the lateral wicking rate is rapid at every depth of the membrane, rather than simply at one narrow level, which is the case with the asymmetric

structure. A purely isotropic structure, however, suffers from relatively poor filtration capabilities. Large cells are not filtered out prior to contacting the smaller pore openings. Rather, the small pore openings at the surface of an isotropic membrane can cause relatively fragile cells, such as blood cells, to lyse and release their contents. Those contents then mix with and contaminate the plasma. The large blood cells (red blood cells, white blood cells, and platelets) in whole blood will also plug the isotropic structure so as to the blood separation rate is much slower than the asymmetric structure, which, because of its better filtration capabilities, does not have the problem of cells lysing at the layer of small, capillary active pores. Membranes having a funnel-with-a-neck structure exhibit plasma transfer rates superior to those of asymmetric membranes, which is very important in diagnostic testing devices, and filtration capacities superior to those of isotropic membranes. The funnel-with-a-neck structure embodies the advantages of both asymmetric and isotropic structures. Rather than having just a single thin layer of small pores in the middle of the membrane, the funnel-with-a-neck structure has a region of small pores comprising a significant thickness of the membrane's cross section, comparable to the neck of a funnel. Throughout this region of smaller pores, lateral wicking occurs in a much shorter time than in regions where the pore sizes are larger. In addition, the tapering region of the funnel-with-a-neck structure serves to filter out the large cells before they can contact the region of small pores, thus eliminating the problem of cells lysing and contaminating plasma prior to lateral wicking – an advantage over isotropic membranes. The funnel-with-a-neck structure exhibits filtration capabilities that are comparable those of classic asymmetric membranes. And because it also demonstrates significantly greater speeds of lateral wicking, the funnel-with-a-neck structure has clear advantages over classic asymmetric membranes in this area.

4. Accordingly, the filter laminates prepared from funnel-with-a-neck membranes offer advantages over filter laminate prepared from membranes as disclosed in Karbachsch and Miller, which are limited to various combinations of isotropic membranes and classic asymmetric membranes. Neither Karbachsch nor Miller teaches or suggests filter laminates incorporating membranes having a funnel-with-a-neck pore structure. Karbachsch discloses a structure, e.g., as in Figure 3, wherein an asymmetric layer is used in combination with two isotropic layers.



5. In contrast, Claim 1 as amended is directed to a filter laminate wherein one layer has a funnel-with-a-neck pore structure, and the other is a porous layer. When the other porous layer is isotropic, for example, the resulting laminate has the following structure.



6. Claim 21 is directed to a filter laminate having "a first membrane layer comprising a first membrane, wherein said first membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface; a second membrane layer comprising a second membrane, wherein said second membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface; and a bond between each of said adjacent layers, wherein said bond is between the skin surface of the first membrane and the skin surface of the second membrane, wherein the filter laminate has a higher bubble point than either the first membrane or the second membrane, and wherein the filter laminate has a greater integrity than a combination wherein the skin surface of the first membrane and the skin surface of the second membrane are adjacent to each other but not bonded to each other, wherein the filter laminate has a flow rate therethrough such that the filter laminate is configured for separation by filtration." Such a configuration can be depicted schematically as follows.

7. As discussed in the present application as filed at page 10, ll. 11-21, a skin-to-skin configuration of two asymmetric membranes, as depicted above, dramatically increases the bubble point of the resulting filter laminate above that of either of the single layers, due to the fact that the probability of lining up two large pores (which are responsible for the bubble point) is significantly reduced because most of the pores are "average" size, and probability greatly favors the situation where a large pore is confronted by numerous smaller pores. This results in greatly improved membrane integrity and, therefore, improved bacterial and particle retention. Simply placing two asymmetric membranes together, skin-to-skin, without bonding them, will not necessarily reduce the bubble point because the test air that flows through the top layer can travel laterally until it finds a larger pore in the bottom layer. Neither Karbachsch nor Miller teaches or suggests such a skin-to-skin bonding configuration between two asymmetric membranes, much less offers any suggestion as to the advantages provided.

8. I declare that all statements made herein are true, and that all statements made upon information and belief are believed to be true, and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that willful, false statements may jeopardize the validity of the application, or any patent issuing thereon.

Dated: 11/14/07

I-Fan Wang
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